

## REMARKS

In this amendment, a correction to the specification has been made in order to more properly treat a third party trademark by giving it distinctive treatment in the text, and using it as an adjective. Since "EUDRAGIT" is a registered trademark, the designation ® is also used. No new matter is introduced by such amendment to the specification.

### **I. The 35 U.S.C. §112 Second Paragraph Rejection**

Claims 25 and 28 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for the reasons stated in paragraph 4 of the communication mailed January 15<sup>th</sup>.

Upon entry of the instant amendment, such rejection will be moot. In the newly added claims, the term "high density" is not employed. Instead, the polyethylene material that forms the body and the cap of the invention is defined by its hardness and its steam permeability. Concerning the Examiner's position regarding "elongation," the Examiner's attention is respectfully drawn to the specification at page 9 where elongation is described and defined. The term "elongation" refers to the relationship between the length and width of the capsule, the capsule now being restricted to a cylindrical shape. Mathematically, such relationship is not presented in terms of units of measure. However, if the length of the capsule is 1 cm, and the width of the capsule is 0.5 cm, and that would result in a determination of 2 for the elongation of such capsule.

Concerning the use of the term "acrylresin" in Claim 28, such term is not employed in the newly added claims. However, it is not a trademark as suggested by the Examiner, and applicants' attorney could locate no United States registered trademark that incorporates such term. Rather, it is a technical term meaning a resin (which is some kind of solid polymer with a net structure), and further this polymer is based on an acryl-polymer. In newly added claim 39, the term used is "an acryl-polymer resin."

## **II. The 35 U.S.C. §102 Rejection**

Claims 16, 18-24 and 26-29 have been rejected under 35 U.S.C. §102 as being anticipated by Etani U.S. Patent 4,692,314 ('314) or Etani U.S. Patent 4,880,547 ('547)

Upon entry of the instant amendment, such rejected claims will be canceled. It is respectfully submitted that newly added claims 31 through 40 are patentable over both Etani patents. In newly added claim 31, from which all newly added claims are dependent, the elongation of the capsule according to the subject application and invention is greater than one. Both Etani patents, disclose spherical capsules which are different from the instantly claims capsules of claim 31 in that the elongation is different. Additionally, the capsule of Etani '314 comprises a number of small holes within the capsule walls. The capsule of the present invention does not have such small holes, as such holes would allow the dry, powdered pharmaceutical formulation to escape or leak from the capsule.

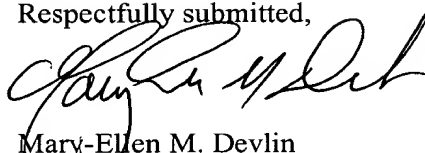
## **III. The 35 U.S.C. §103 Rejection**

Claims 16-29 have been rejected under 35 U.S.C. §103 as being unpatentable over EP 0143,524 (EP'524) in view of Jones U.S. Patent 4,892,766, Etani U.S. Patent 4,880,547 ('547) and Lee et al. U.S. Patent 5,795,591.

In view of the cancellation of Claims 16 through 29, and the presentation of new claims 31 through 40, reconsideration of the rejection under Section 103 is respectfully requested. The present invention is directed at capsules having dry, powdered pharmaceutical formulations, which capsules have a certain shape and are made of material not generally associated with pharmaceutical preparations, that is hydrophobic material that is not digestible. The capsule material also possesses certain defined hardness characteristics. In particular, the present invention provides capsules particularly suitable for dry formulations, that is, for formulations that are either sensitive to moisture (degradation) or formulations that will not flow or be easily administered if there is moisture contact. None of the references cited by the Examiner teach the instantly claimed combination. The filled capsules of the present invention are to be used in dry powder inhalation devices. None of the cited references disclose such type of capsules, or anticipates such use of capsules.

In view of the foregoing, reconsideration of the rejections is respectfully requested.

Respectfully submitted,



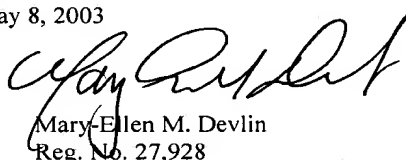
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on May 8, 2003



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